REMARKS

Claims 9-15 presently appear in this case. No claims have been allowed. The official action of June 10, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

The present invention relates to a method for treating a neurological disease or disorder, such as MS, Alzheimer's Disease, Parkinson's Disease or ALS, by administering to a patient in need thereof an effective amount of IL6RIL6 chimera.

Claims 5-13 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The examiner states that the specification as filed does not describe the structure of the IL6RIL6 chimera, as an adequate written description requires more than a mere statement that it is part of the invention. The examiner notes the disclosure that the claimed chimera is a recombinant glycoprotein obtained by fusing the entire coding sequence of the naturally-occurring hsIL-6 receptor δ-val to the entire coding sequence of mature naturally-occurring IL-6. However, the examiner states that the specification does not disclose the structure of that chimera, i.e., one would not be able to visualize the claimed chimera. The examiner notes applicants' reference to WO 99/02552, but

states that it refers to several different chimera. Thus, the examiner concludes that one of ordinary skill in the art would not know from the instant disclosure whether or not a linker peptide is to be used, and that the inventors were not possession of a pharmaceutical composition comprising the chimera of IL-6 receptor and IL-6. This rejection is respectfully traversed.

The examiner recognizes that the claimed IL6RIL6 chimera is not something novel to the present specification. It is something that is known in the prior art, and this knowledge in the prior art is well referenced in the present specification. In the last full sentence on page 3, the background of the invention refers to the production of IL6RIL6 chimera and references a 1997 publication from the laboratory of the present inventors and a 1999 PCT publication, again from the laboratory of the present inventors, both of which were published prior to the effective filing date of the present application. The meaning of the term "IL6RIL6 chimera" is well defined in the prior art WO 99/02552 publication. As seen on page 5 of this publication, such a chimera comprises essentially all of the naturally-occurring sIL-6R from human body fluids and essentially all of the mature form of the naturally-occurring human IL-6. They may be separated by short linker peptides, which can be as

short as three amino acids in length or longer, for example 13 amino acids in length, or the linker may be omitted. The C-terminal Val on the sIL-6R may be omitted. The two components are interchangeable, i.e., either one may be upstream of the other.

The WO 99/02552 publication is incorporated by reference in the present specification, see page 7, lines 19-28, and page 12, lines 4-8. Thus, it seems rather inappropriate to state that the present inventors were not in possession of this chimera. They invented the chimera, disclosed it in publications and patent applications, and reduced it to practice prior to the effective filing date of the present application. These facts were noted in the specification and, therefore, the written description requirement is satisfied. It is not necessary to describe that which is already well known in the art. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986) ("A patent need not teach, and preferably omits, what is well known in the art."); *Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 231 USPQ 649, 653 (Fed. Cir. 1986) ("A patent applicant need not include in the specification that which is already known to and available to the public."); and *In re Wands*, 8 USPQ2d 1400, 1402 (Fed. Cir. 1988) ("A patent need not disclose what is well known in the

art."). Thus, it is not necessary for the specification to disclose the structure of that chimera to those of ordinary skill in the art aware of the prior art incorporated by reference into the specification. One already knows what the structure of the chimera is. Thus, if it has already been visualized in the prior art, certainly one of ordinary skill in the art reading the present specification would be able to visualize it.

The examiner states that WO 99/02552 refers to several different chimera. This is not entirely correct. WO 99/02552 defines sIL-6R/sIL-6 in such a way that it may include a number of embodiments, all of which fall into the definition of the chimera, but there is no doubt about what the definition is. Chimeric sIL-6R/sIL-6 proteins (i.e., IL6RIL6 chimera) are described, as well as biological active analogs thereof. Note the examples of embodiments at pages 7-9. It can be seen from paragraphs (v) and (vi) on page 8 that the sIL-6R δ Val/IL-6 is an embodiment of a chimeric sIL6R/IL6 protein and not an embodiment of the biologically active analogs thereof. That the δ-Val embodiment is considered to be within the definition of IL6RIL6 chimera is evident from page 7, lines 19-28, of the specification.

Accordingly, applicants were in possession of the structure of the chimera, and anyone of ordinary skill in the

art would know the structure of the described chimera by reviewing the prior art particularly mentioned and, indeed, incorporated by reference in the specification. Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

Claims 5-13 have been rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the enablement requirement thereof. For claims 5-8, the examiner states that the claims encompass a pharmaceutical use and that for the claims to be enabled the specification must teach how to use the composition for at least one therapeutic use without undue experimentation. For claims 9-13, the examiner states that the specification does not disclose or describe one single method in which any of the recited diseases or disorders have been treated using the chimera of the present invention, and thus, the specification is not enabling. The examiner states that in Example 8 there is no demonstration that the chimera improves the clinical score of the mice. This rejection is respectfully traversed.

The composition claims have now been deleted. With respect to the method claims, clinical testing is not necessary in order to establish utility and enablement for an invention. Utility and enablement exist if those of ordinary skill in the art reading the specification would not doubt the

credibility of the statements of use that are now claimed. The *in vitro* experiments establish the expectation that the invention will work *in vivo*. The issue here is whether the experimentation needed to practice the invention is undue or unreasonable. There is no reason to believe that the experimentation necessary to take the present invention to the clinic would be undue or unreasonable. MPEP §2164.02 states that an *in vitro* example in the specification, in effect, constitutes a "working example" if that example correlates with a disclosed or claimed method invention. The remyelination experiments do, indeed, correspond to the claimed method of treating MS, for example. Accordingly, as the disclosed utility is not incredible, and as those of ordinary skill in the art would know how to go about using the invention in the claimed methods without undue experimentation, reconsideration and withdrawal of this rejection are respectfully urged.

Claims 5-13 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite. The examiner states that the phrase "optionally" renders the claims indefinite and the recited acronyms are unclear.

The claims have now been amended to delete the "optionally" phrase and to insert the full meaning of the acronyms, thus obviating this rejection.

Claims 5-8 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 99/02552.

Claims 5-8 have now been deleted, thus obviating this rejection.

It is submitted that all the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are, therefore, earnestly solicited.

Respectfully submitted,

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